

JUL 07 2005

**GODBEY GRIFFITHS REISS CHONG**  
ATTORNEYS AT LAW

1001 BISHOP STREET  
SUITE 2300 - PAUAAH TOWER  
HONOLULU - HAWAII 96813  
808 - 523 - 8894  
FAX - 523 - 8899  
WWW.LAWHI.COM

ROBERT CARSON GODBEY  
JESS H. GRIFFITHS  
SETH M. REISS  
LEIGHTON K. CHONG  
CHAD M. IIDA  
  
DANIEL BENT  
G. FRED JEYNES  
OF COUNSEL

**FORMAL COMMUNICATION BY FACSIMILE TO  
THE UNITED STATES PATENT AND TRADEMARK OFFICE**

To: Blessing Fubara (Examiner)  
CT/A.U. 1618, United States Patent & Trademark Office

Date: July 7, 2005 Fax Nos.: (571) 273-8300  
From: Seth M. Reiss, Esq.  
Re Application No.: 09/596,362  
Confirmation No.: 1986  
Attorney Docket No.: 4171-1P  
Total Number of Pages: 6 (including this cover page)

Name of Operator: Cristine Yerxa/Legal Assistant to Seth Reiss  
If message not received properly, please contact me as soon as possible.

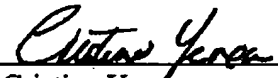
\*\*\*\*\*

REMARKS: REPLY AND REQUEST FOR RECONSIDERATION AFTER  
FINAL PURSUANT TO 37 CFR § 1.116

**CERTIFICATE OF FACSIMILE TRANSMISSION**

I hereby certify that this paper and the papers described as attached are being  
facsimile transmitted to the U.S. Patent Office on the date show below.

Date: July 7, 2005.

  
Cristine Yerxa  
Legal Assistant to Seth Reiss

THE INFORMATION CONTAINED IN THIS FACSIMILE MESSAGE AND THE INFORMATION ATTACHED  
HERETO IS CONSIDERED PROPRIETARY, PRIVILEGED AND CONFIDENTIAL. IF THE READER HAS  
RECEIVED THIS COMMUNICATION IN ERROR, PLEASE CONTACT THE SENDER BY CALLING US AT (808)  
523-8894, AND DESTROYING THE FACSIMILE MESSAGE OR RETURNING IT TO US AT THE ABOVE ADDRESS.  
YOUR COOPERATION IS APPRECIATED.

Serial No. 09/596,362  
Reply and Request for Reconsideration After Final  
Honolulu, Hawaii, July 6, 2005

Dear Examiner Fubara,

As per our discussion regarding what makes my patent submission novel and new are two factors. The first is the use of kavapyrones to treat the craving of alcohol addiction and second factor is the administration of kavapyrones while the patient is continuing to consume alcohol.

My double blind study presented in the specification found that when kavapyrones are administered to patients addicted to and currently consuming alcohol there was a statistically significant percentage of patients achieving and maintaining sobriety over the control group.

The use of kavapyrones to reduce alcohol consumption was never previously reported. There is no report of kava or kavapyrones being used to treat alcohol craving or to achieve sobriety. The treatment of withdrawal symptoms is for the treatment of a patient who has ceased consuming alcohol and is suffering the consequences. The literature clearly distinguishes between dependence treatment, which is associated with why a patient cannot achieve sobriety, and withdrawal symptoms, which have nothing to do with assisting a patient in reaching sobriety. An alcoholic craves alcohol while consuming alcohol and therefore is driven to continue to drink. The alcoholic who is drinking has no withdrawal symptoms. It is the drinking alcoholic that my invention treats.

We have an endless array of medications to treat withdrawal symptoms but very few drugs have been shown to assist the alcoholic in achieving and maintaining sobriety as is reported in my specifications. In your office communication you state "The American Family Physician article provided by the applicant recognizes that treatment of withdrawal should be followed by the treatment of dependence". This is correct because they are two different entities and they must to be treated differently. But your statement also confirms the novel nature of my invention because I treat the dependence before withdrawal symptoms and while the patient is still consuming alcohol.

Also, the article is talking of forcibly preventing the alcoholic from drinking by confinement. Currently treating addiction by confinement and waiting for the cravings to naturally reduce is the way addicts are treated. The administration of kavapyrones to reduce craving while the patient is drinking is one aspect that makes my invention novel. My invention as established by my research is administered to an alcoholic while he is drinking and the alcoholic stops drinking because he no longer craves (desires) alcohol. My invention has shown that an alcoholic can carry on a normal life while being treated rather than being locked into a treatment center and forced into withdrawal.

Because we do not have effective treatments for the craving for alcohol, the state of the art is to forcibly withdraw alcohol and then attempt to treat the craving. Science will develop effective medications for craving and at that time addictions will no longer be the scourge on society it is today. My invention is an early step in a field that is just beginning to realize that someday we

will have effective medications for addiction that will not require extended stays in rehabilitation centers.

Cherksey has described a group of compounds that have a formula that excludes the kavapyrones. Cherksey repeatedly states that the group of compounds are for treating the symptoms of addiction and nicotine withdrawal. At no time does Cherksey discuss kavapyrones in relationship to addiction. Cherksey claims that kavapyrones are potassium channel activators but does not include the kavapyrones in his research regarding potassium channel activators. Cherksey claims kavapyrones are potassium channel activators but cites no references that establish this as factual. In a literature search of all published research at no time were the kavapyrones stated to be potassium channel activators.

When Umbdenstock discusses alcohol craving he specifies the formula he has devised for treating the craving of alcohol which never mentions kava. Umbdenstock teaches a nutritional formula designed to "resist the cravings that accompany withdrawal symptoms".

Thank you for your consideration.

Sincerely,

Greg Steiner